SPECIMEN COLLECTION FORM for Baseline Post-Transplant Visit (TL02)

CKiD Chronic Kidney Disease in Children Cohort Study (CKiD) SECTION A: GENERAL INFORMATION

A1.	PARTICIPANT ID: A	FFIX ID LABEL (OR ENTER N	IUMBER	IF ID LA	BEL IS NO	ΓAVAILABLE
			-	· ·	-	_	
A2.	CKiD Post KRT VI	SIT #:			_		
A3.	FORM VERSION:		_0_	7 /	0 1	/ 1	<u>9a</u>
A4.	SPECIMEN COLL	ECTION DATE:		/ M D	//	YY	Y
A5.	FORM COMPLETI	ED BY (INITIAL	S):				
At the Post	-Transplant Baseli	ne V1b Visit ar	nd if conser	nt is obta	ained, c	ollect the	following:
Samples:		Shipped to:			Shippe	<u>d:</u>	
Serum (Bio	logical)	NIDDK Biorep	ository		Batche	d (Ship in .	Jan, Apr, Jul or Oct)
Plasma (Bio	ological)	NIDDK Biorep	ository		Batche	d (Ship in 、	Jan, Apr, Jul or Oct)
Urine (Biole	ogical)	NIDDK Biorep	ository		Batche	d (Ship in 、	Jan, Apr, Jul or Oct)
В	Samples s	S SHOULD BE OFTEN IF DES should NOT be fic questions,	SIRED BY T stored for	HE SITE	COORI an six (6	DINATOR 6) months	! ´ ´ ´ .
	т от орост			-		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
		SECTION	B: PREGNA	INCY IE	:51		
B1. Is	participant a female of	of child-bearing p	otential?				
Ye	es	1	(See PROM	PT Below	v)		
No.	0	2	(Skip to Sec	tion C)			
URINE P	T: QUESTION B2 IS I PREGNANCY TEST DE ESTUDY VISIT DATE	PATE MUST OCC	_				_
B2. a.	Urine pregnancy te	st date: _	/	/	<u></u>	Y	
b.	Urine pregnancy re Positive		(END; COM	PLETE T	RANSIT	IONAL (TR	S03) FORM)
	Negative		-			`	, ,



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SECTION C: V1b POST-TRANSPLANT VISIT B BLOOD DRAW

If participant consented to BIOLOGICAL samples:

Collect 9 mL if participant is < 30 kg OR 15 mL if participant is $\ge 30 \text{ kg}$.

If < 30 kg, immediately transfer or draw:

- 6 mL into (1) Tiger-Top SST for NIDDK Biorepository
- 3 mL into one (1) PST for NIDDK Biorepository

If ≥ 30 kg, immediately transfer or draw:

- 10 mL into (2) Tiger-Top SSTs for NIDDK Biorepository
- 5 mL into (2) PSTs for NIDDK Biorepository

V1b POST-TRANSPLANT VISIT BLOOD DRAW PROCESSING NIDDK BR (Serum) NIDDK BR (Plasma)

Invert the Tiger Top SST 5 times gently to mix.

Stand SST upright to allow clotting at room temperature for 30 mins and not more than 1 hour (60 mins).

Centrifuge SST at MAX SPEED between 1100-1300g (3000rpm with 10cm radius rotor) for 10 mins in swinghead OR 15 mins in fixed angle.

*If incomplete separation, centrifuge again 10-15 mins.

Invert each PST 8-10 times gently to mix.

Centrifuge each PST at MAX SPEED between 1100-1300g for 10 mins (swinghead) **OR** 15 mins (fixed angle).

NIDDK (Serum)

Pipette 3 mL (<30kg) or 5 mL (≥30kg) serum into clear top cryovial (use different pipettes for serum and plasma). *If there is any extra serum, then pipette the extra serum into the clear top cryovial marked "NIDDK BR SERUM".

NIDDK (Plasma)

Pipette 1.5mL (<30kg) or 2.5mL (≥30kg) plasma into cryovial with green cap insert (use different pipettes for serum and plasma).

*If there is any extra plasma, then pipette the extra plasma into the green cap insert cryovial marked "PLASMA (Extra)".

Complete SM01 form, store sample(s) in freezer at -70°C or lower, batch up to 40 samples and ship on dry ice quarterly (**January, April, July and October**) to the NIDDK BR. **No Thursday/Friday shipments** When shipper is needed, complete "NIDDK BR Dry Ice Shipper Request Form" on the CKiD website: https://statepi.jhsph.edu/ckid/coordinator-resources/. Then, follow packaging instructions.

When pickup has been scheduled, complete "On-line Shipping Form" on CKiD website: https://statepi.jhsph.edu/ckid/coordinator-resources/ to notify the appropriate personnel from the CBL and the NIDDK BR.

SECTION C: NIDDK BIOREPOSITORY

C1.	Did the participant consent to have biological sam	ples (i.e., serum	, plasma and urine	samples) stored at the	NIDDK Biorepository?
	Yes	1			
	No	2 (END)			

Reasons Code List*:	1= Not required	4 = Red Blood Cell Contamination	7 = Exceed maximum allowable volume
	2 = Difficult Blood Draw	5 = Inadvertently Destroyed	
	3 = Participant Refused	6 = Oversight	

	Sample Type (Required Volume in Top Color Tube Type):	(a) Sample Obtained:		(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:	
		<u>Yes</u>	<u>No</u>	SEE CODE LIST ABOVE		
C2.	Serum for NIDDK Biorepository (**6.0 mL or **10.0 mL of blood in Tiger Top SST)	1 (skip to c→)	2	(skip to C3)	Date Frozen:/	
C3.	Plasma for NIDDK Biorepository (***3.0 mL of blood in one Green Top or ***5.0 mL in two Green Top PSTs)	1 (skip to c→)	2	(skip to D1)	Date Frozen:/	

^{**} Collect 6.0 mL of whole blood for participants < 30 kg and 10.0 mL for participants ≥ 30 kg

^{***} Collect 3.0 mL of whole blood for participants < 30 kg and 5.0 mL for participants \ge 30 kg

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SECTION D: URINE COLLECTION AND PROCESSING FOR REPOSITORY

Collect FRESH urine into an initial urine collection cup or hat (provided by the site).

Pour 15-60 mL (preferably 60 mL) of FRESH urine into 90 mL urine collection cup with 4 protease inhibitor tablets. Do not fill the urine past the 60 mL mark on the collection cup. One protease inhibitor tablet should be used for 10-15 mL of urine (see Table A). For example if 30 mL of urine is collected, ONLY 2 protease inhibitor tablets are needed. (Like all unused supplies, unused protease inhibitor tablets should be returned to the CBL.)

Invert the urine cup gently 5 - 10 times.

The PROTEASE INHIBITOR TABLET(s) MUST BE COMPLETELY DISSOLVED in the urine.

 $\begin{array}{c|c} \textbf{TABLE A:} & \# \ \text{of Protease} \\ \hline \textbf{Urine Volume} & \hline 10-15 \ \text{mL} \\ 16-30 \ \text{mL} & \textbf{2} \\ 31-45 \ \text{mL} & \textbf{3} \\ 46-60 \ \text{mL} & \textbf{4} \\ \end{array}$

Once the protease inhibitor tablet(s) are completely dissolved, pour urine into up to six (6) 10 mL urine centrifuge tubes. (For each tube: remove yellow top cap, pour urine into tube and SCREW cap back onto tube.) Place no more than 10 mL in each tube.

-- OR -

Sites may also substitute with tubes normally used to centrifuge urine at site.

Centrifuge urine tube(s) at MAX SPEED between 1100-1300g (3000rpm with 10cm radius rotor) for 10 mins (swinghead units) – **OR** – 15 mins (fixed angle units).

Decant (pour off) the supernates (liquid reaction) into up to seven (7) 10 mL urine cryovials. Pour no more than 9 mL of urine into each 10 mL cryovial to allow for expansion.

Check that all information is correct on the urine cryovials, complete the SM01 form and promptly freeze and store sample(s) at -70°C or lower. Batch samples and ship on dry ice at least quarterly (include maximum of 36 cryovials per shipper). When shipper(s) is needed, complete "NIDDK BR Shipper Request Form" on CKiD website: https://statepi.jhsph.edu/ckid/coordinator-resources/. Then, follow packaging instructions. No Thursday/Friday shipments.

When pickup has been scheduled, complete "Online Shipping Form" on CKiD website to notify the NIDDK and KIDMAC that sample(s) have been shipped to NIDDK BR.

Reas	sons Code List [*] :	1= Not required	2 = Difficult Urine Collection	3 = Participant Refused	4 = Collection Contamination	5 = Inadvertently Destroyed	6 = Oversight	7 = Insufficient volume	
	Sample Type (Required Volume in Top Color Tube Type):			(a) Sample Obtained: Yes No	(b) If No, specify reason *SEE CODE LIST ABOVE	(c) Additional Requirements:			
	D1. Urine for NIDDK Biorepository (15.0 - 60.0 mL of urine in specimen container and transferred into collection cup with protease inhibitors)		d transferred into	1 2 (skip to c→)	(skip to END)	i. Was supernate decanted into urine transport cryovials? Yes			